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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,475	07/31/2003	Derek O'Hagan	PP01388.211	3256

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,475	O'HAGAN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,11-14,17-26,28-35,40-42 and 52-91* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9,11-13,34,35,52-54,56-59,61-63,68,69,74,75,86 and 87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-19-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-26,28-33,38,40-42,55,60,64-67,70-73,76-85 and 88-91.

DETAILED ACTION

Election/Restrictions

1. Claims 1-4, 6-9, 11-14, 17-26, 28-35, 28, 40-42, and 52-91 are pending in the present application.

2. Applicant's election with traverse of Group I, and the inventions wherein the polymer is the poly(α-hydroxy acid) poly(D,L-lactide-co-glycolide), the antigen is a polynucleotide encoding a meningitis B antigen, the antigen is adsorbed to the surface of the microparticle, and the adjuvants is a CpG oligonucleotide in the reply filed on October 12, 2004 is acknowledged.

The Applicant traverses the restriction on two grounds.

First, the Applicant argues that the different inventions are not independent in the same manner as a locomotive and a shoe. However, the different inventions are drawn to different inventions that meet the requirements for restriction as expressed in the MPEP. See, restriction requirement, pages 3-4. Further, even if the claims are not independent in the same manner as a locomotive and a shoe, the different inventions nonetheless represent distinct inventions that are not structurally related. Additionally, it is noted that the Examiner acknowledges the presence of certain linking claims among the inventions, and that, if the linking claims are found allowable, the restriction among the different inventions will be withdrawn.

Second, the Applicant argues that situations where independent inventions are independent are rare. However, the Applicant has not provided any evidence that the different inventions identified in the restriction requirement are not either distinct or independent. The Applicant has not provided anything more than a mere assertion that the inventions, identified as

unrelated in the restriction requirement, should not be separated. This assertion is not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 7, 8, 14, 17-26, 28-33, 38, 40-42, 55, 60, 64-67, 70-73, 76-85, and 88-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 12, 2004.

4. Currently, claims 1-4, 6, 9, 11-13, 34, 35, 52-54, 56-59, 61-63, 68, 69, 74, 75, 86, and 87 are under examination to the extent that they read on the elected invention, or are generic thereto.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on December 19, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

6. It is noted that Foreign Patent Document No. 5 has been crossed out on the December 2003 IDS. This reference is the same as Foreign Patent Document No. 1 in the same IDS. Thus, the reference has already been made of record and considered.

Priority

7. It is noted that the Applicant has amended the present application to refer to the parent applications in the Response to Restriction Requirement submitted on October 12, 2004. However, under 37 CFR 1.78(a)(2)(ii), the required reference must be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Under 37 CFR 1.78 priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional.

Because the Applicant did not amend the application to contain the required reference until after the indicated periods, and because no grantable petition for a delayed claim for priority has been filed, the requirements of 37 CFR 1.78 have not been met

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 6, 11, 13, 34, 35, 59, 61-63, 74, 75, 86 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (WO 96/20698- of record in the December 2003 IDS). These claims read on microparticles comprising a biodegradable polymer, particularly a poly(α-hydroxy acid), a cationic detergent, and an immunological adjuvant adsorbed to the surface. Such particles are described by the Levy reference. See e.g., pages 6-9. The reference teaches that the bioactive agents, including adjuvants and antigens (pages 8 and 10, may be incorporated into, or adsorbed onto the particle (page 15, second paragraph). The document also teaches that surfactants and detergents may be incorporated into the particle (page 15, first paragraph), and indicates that such incorporation helps with the incorporation or attachment of the bioactive agent (e.g. page 16, second full paragraph). The reference therefore teaches compositions according to the present claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-4, 6, 11, 13, 34, 35, 58, 59, 61-63, 68, 69, 74, 75, 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (WO 96/20698), in view of Coombes et al. (Vaccine 14: 1429-38- of record in the December 2003 IDS). These claims have been described in part above. Claim 58 limits the claims to embodiments wherein the particles have a

diameter between 500 nm and 30 microns. The teachings of Levy have also been described above. While the reference teaches the use of the claimed particles, the reference indicates that the preferred size is under 300 nm. However, Coombes teaches particles of similar construction to those of Levy, and indicates that the particles are effective at inducing immune responses up to 72 microns, although they are most effective when the particles have a diameter of under 10 microns. From these teachings, it would have been obvious to those in the art to construct the particles as suggested by Levy for use in immunogenic compositions wherein the particles have a diameter according to the teachings of Coombes. The teachings of these references therefore render the claimed inventions obvious.

12. Claims 1-4, 6, 11-13, 34, 35, 52, 53, 58, 59, 61-63, 68, 69, 74, 75, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy or Levy in view of Coombes, and further in view of Krieg et al. (U.S. 6,207,646). These claims read on microparticles, and compositions thereof, comprising an adjuvant adsorbed to its surface, particularly, wherein the adjuvant is a CpG oligonucleotide. The teachings of Levy have been described above. As was noted above, Levy teaches a vehicle for the delivery of antigens comprising surface-modified particles formed out of a biodegradable biopolymer, wherein antigens and adjuvants may be either incorporated into the particle, or attached to its surface. Pages 15-16. However, the reference does not specifically identify CpG oligonucleotides as potential adjuvants.

Krieg teaches the use of CpG containing nucleotide sequences as immunostimulants. Because Levy teaches that the particles described therein may include 1) DNA molecules, and 2) adjuvants either within or adsorbed to the surface of the particles, it would have been obvious to

those in the art to make particles according to Levy (or Levy in view of Coombes) wherein the adjuvant is a CpG containing oligonucleotide, and to make such particles wherein the oligonucleotide is within the particle, adsorbed to it, or both. The teachings of these references therefore render the claimed inventions obvious.

13. Claims 1-4, 6, 9, 11-13, 34, 35, 52-54, 57-59, 61-63, 68, 69, 74, 75, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy or Levy in view of Coombes as applied above, and further in view of Davis et al. (WO 98/40100). The claims have been described in part above. Certain of these claims are directed to embodiments wherein the antigen "comprises a polynucleotide" and wherein the "antigen comprises a plasmid DNA molecule." As indicated above, Levy teaches that polynucleotides and adjuvants may be incorporated and adsorbed onto the described particles. From the teachings of Levy, it would appear that the described methods of incorporating the polynucleotides into the microspheres would inherently result in the adsorption of at least some of the polynucleotides onto the surface of the resulting particles. However, the reference does not explicitly teach that the polynucleotides are the antigen or that they may comprise plasmid molecules, nor does the reference teach the use of CpG adjuvants with such antigens.

However, Davis teaches the combination in a pharmaceutical composition of a polynucleotide encoding an antigen and a CpG oligonucleotide adjuvant. See e.g., claims 28, 33, 35, 36, and 127. The reference also teaches the association of the polynucleotides with carrier molecules such a liposomes or virosomes. Page 9. The reference does not however suggest the use of a particle such as that disclosed by Levy or Levy in view of Coombes. However, because

Levy indicates that the particles disclosed therein may be used to delivery DNA molecules, and because Davis indicates that similar types of carriers may be used to deliver the CpG/plasmid compositions disclosed therein, it would have been obvious to combine the teachings of these references to result in the claimed compositions. Those in the art would have had a reasonable expectation of success in such a combination because the art teaches that microparticles of similar design to those of Levy have been known to be able to successfully delivery encapsulated DNA. See e.g., Hedley et al., U.S. Patent 5,783,567 columns 14-18(teaching the expression of polynucleotides delivered to cells in PLGA microparticles -of record in the December 2003 IDS). See also, Jones et al., Vaccine 15: 814-17. In view of these teachings, it would have been obvious to those in the art to make microparticles such as those claimed for the delivery of DNA encoding antigens, and an adjuvant (including CpG oligonucleotides) to an animal.

14. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy or Levy in view of Coombes as applied above, and further in view of any of Carlo et al. (U.S. 4,413,057- of record in the December 2003 IDS), Blake et al. (U.S. Patent 5,747,287), and Dlawer et al. (Vaccine 14: 49-53). Claim 56 further limits the particles of claim 2 to embodiments wherein the antigen is an antigen against meningitis B. The teachings of Levy and Levy in view of Coombes have been described above. These references do not teach the use of the presently claimed antigens, although they do suggest the inclusion of any antigen in the disclosed particles. Because the additionally cited references both teach anti-N. meningitides B antigens, and indicate that the induction of an immune response against such antigens would be desirable, it would have been obvious to those in the art to make particles according to Levy or Levy in view

of Coombes comprising the antigens of the additionally cited references. The combined teachings of these references therefore render the claimed invention obvious.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-4, 6, 9, 11-13, 34, 35, 52-54, 56-59, 61-63, 68, 69, 74, 75, 86 and 87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 11, 13, 14, 15, 43, 45-47, 56, 71, 72, 77-86, 89, 90, 104, and 105 of copending (now allowed) Application No. 09/581,772. The claims of the copending application, although not identical to the present claims, read on obvious variations of the presently claimed inventions.

This is a provisional obviousness-type double patenting rejection.

17. Claims 1, 3, 4, 6, 11, 12, 34, 35, 52, 53, 58, 59, 61-63, 68, 69, 74, 75, 86 and 87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9, 10, 22-25, and 47-51 of copending Application No.

10/357,303. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application represent a species of the presently claimed inventions. Because the claims of the copending application would anticipate the (provisionally) rejected claims of the present application, the present claims are rejected for obviousness type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1- 4, 6, 11-13, 34, 35, 52-54, 56, 58, 59, 61-63, 68, 69, 74, 75, 86 and 87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-7, 9, 11, 23, 25, 27, 29, 37, 39-41, 49, 51-53, 54, 58, and 59 of copending Application No. 10, 264,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application represent a species of the presently claimed inventions. Because the claims of the copending application would anticipate the (provisionally) rejected claims of the present application, the present claims are rejected for obviousness type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-4, 6, 9, 11-13, 34, 35, 52-54, 56-59, 61-63, 68, 69, 74, 75, 86, and 87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 42 of copending Application No. 10/775964. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claim of the copending application are generic to the claims of the present application, and because the specification of the copending application teach, or render obvious, the limitations of the claims in the current application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is

based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 12/26/04
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